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10/534,403	12/19/2005	Oleg Bassovitch	52-05	2873

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT	PAPER NUMBER
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3771

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11/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,403

Applicant(s)

BASSOVITCH, OLEG

Examiner

Annette F. Dixon

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9,12,19,21-23 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9,12,19,21-23 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s) :

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/27/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed on September 27, 2007. Examiner acknowledges claims 1-5, 9, 12, 19, 21-23, and 26, with claims 1, 2-4, 9, 12, 22, and 23 having been currently amended, claim 26 having been newly added, and claims 6-8, 10, 11, 13-18, 20, 24, and 25 having been cancelled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5, 9, 12, 19, 21-23, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP §608.04.

Specifically, claim 1 now recite(s) the claim limitations of "the membrane comprised of flexible thermo-conductive material"; however, the originally filed disclosure does not provide evidence that Applicant possessed the newly claimed invention at the time the application was filed. In fact, the original specification of the instant invention discloses a membrane but gives no information as to the material

composition of the membrane. As there is no specific recitation or support for a "thermo-conductive material" in the original disclosure; the subject matter added to the claims is considered new matter and must be cancelled from the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 9, 19, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukunaga (6,874,500) in view of Maddock (4,098,271).

As to Claims 1 and 26, Fukunaga discloses a breathing apparatus for supplying a rebreathable air mixture expired by a user, which air mixture has a lower oxygen concentration than the ambient air, said apparatus comprising: an expiratory path (the flow of 1-2-3-12 and 7-6-8-9-10-11), said expiratory path communicating with a reservoir (10) being formed by a membrane, wherein said membrane is comprised of flexible thermo-conductive material that substantially equalizes the temperature of the expired air in said reservoir (10) with communicating ambient air, thereby providing a means to decrease the dew point of the said expired air in order to reduce the humidity thereof and a means to decrease the temperature of said expired air, wherein said reservoir (10) is contained within a casing (the element holding reservoir, 10, in figure 3C) of selectively variable volume; an inspiratory path (the flow of 1-2-3-4-5-6-7 and 10-12-4-5-

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6-7) communicating with said reservoir (10) through a carbon dioxide absorption chamber (12) wherein said adsorption chamber (12) is positioned downstream of the reservoir (10); and a means of communication of said expiratory path and said inspiratory path in sealed engagement with the respiratory system of a user (via Y tube 6). Yet Funkunaga does not expressly disclose the use of a demand valve in said inspiratory path to facilitate communication with the ambient air as required. However, at the time the invention was made the use of a demand valve in communication with the inspiratory path to facility ambient air as needed was known. Specifically, Maddock teaches an anti-asphyxia valve which opens once the initial gas source has been depleted in order to enable the user to avoid hypoxemia. (Column 1, Lines 41-51 and 56-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Fukunaga to include an anti-asphyxia valve as taught by Maddock to prevent the user from a hypoxic event resulting from a lack of available oxygen.

As to Claim 2, Fukunaga discloses the volume of the reservoir (10) varies from a minimum volume area to a maximum volume area.

As to Claim 9, Fukunaga discloses the reservoir (10) enables the oxygen content to be adjusted by the mixing of air within the reservoir (10) via source (1).

As to Claim 19, Fukunaga discloses the reservoir (10) is disposable.

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6. Claims 3-5, 12, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukunaga (6,874,500) in view of Maddock (4,098,271), and further in view of Lewis et al. (4,764,346).

As to Claims 3-5, Fukunaga/Maddock discloses a breathing apparatus comprising all the recited elements, yet does not expressly disclose the reservoir placed inside a chamber. However at the time the invention was made the use of a chamber to protect the reservoir was well known. Specifically, Lewis discloses a flexible membrane containing purified air being housed inside a chamber for the purpose of enabling the amount of medicament to be delivered to the patient to be specifically monitored enabling efficient rebreathing (Column 2 Lines 45-53). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Fukunaga/Maddock to be placed inside a chamber, as taught by Lewis to enable efficient rebreathing and thereby enabling the compression cycle to be automated.

As to Claims 12, Fukunaga/Maddock discloses a breathing apparatus comprising all the recited elements, yet does not expressly disclose the use of apertures for communicating through the sidewall between said absorptive chamber and adjacent to the sidewall and a flexible material for the reservoir. However, at the time the invention was made the use of apertures was well known. Specifically Lewis teaches the use of apertures (25a) for the purpose of maintaining the pressure within the flexible reservoir. (Figure 4 and Column 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of

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Fukunaga/Maddock to include the apertures (25a), as taught by Lewis for the purpose of maintaining pressure within the system.

As to Claim 22, Fukunaga/Maddock discloses a breathing apparatus comprising all the recited elements, yet does not expressly disclose the carbon dioxide adsorption chamber is located within a canister and is replaceable. However, at the time the invention was made the use of carbon dioxide adsorption chamber having a canister was well known. Specifically Lewis discloses a disposable canister having the carbon dioxide adsorption chamber therein for the purpose of preventing patient contamination. (Figure 4 and Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a disposable canister, as taught by Lewis to prevent contamination and the need for sterilization

As to Claim 23, Fukunaga/Maddock discloses a breathing apparatus comprising all the recited elements, yet does not expressly a constant volume of the reservoir. However, at the time the invention was made the ability to maintain a constant volume was well known. Specifically, Lewis discloses the use of gas inlet line (26) to enable the volume of the reservoir to be maintained by providing additional gas for anesthesia. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the pressurized line, as taught by Lewis to enable additional additives to be provided to the patient.

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7. Claim 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukunaga (6,874,500) in view of Maddock (4,098,271), and further in view of Smith (6,536,430).

As to Claim 21, Fukunaga/Maddock discloses all the recited elements, yet does not expressly disclose the use of an oxygen analyzer within the inspiratory path. However, at the time the invention was made the use of an oxygen analyzer was well known in rebreathing devices. Specifically, Smith discloses the use of an oxygen analyzer (14) for the purpose of ensuring the patient is receiving sufficient oxygen and the rebreathing device is functioning properly. (Column 4, Lines 43-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Fukunaga/Maddock to include an oxygen analyzer, as taught by Smith to ensure proper patient ventilation.

Response to Arguments

8. Applicant's arguments with respect to claims 1-5, 9, 12, 19, 21-23, and 26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lyall (4,596,246)..

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. zStatus information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Annette F Dixon
Examiner
Art Unit 3771



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11/14/07